REMARKS

The Office Action of February 7, 2007, has been carefully considered. In that Action, Claims 6, 7, 9, 11-13, 16, and 28-31 were pending. All claims were objected to and rejected. Applicants respectfully request favorable reconsideration for the reasons below.

Objections

Claims 6, 7, 9, 11-13, 16, and 28-31 were objected to for various informalities.

Applicants have amended Claims 6 and 29 as suggested by the Office and respectfully request favorable reconsideration.

35 U.S.C. §112, second paragraph rejections

Claims 6, 7, 9, 11-13, 16, and 28-31 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. The Office contends that "low" water content is indefinite. Applicants respectfully request favorable reconsideration for the reasons below.

Definiteness of claim language must be analyzed in light of the interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See* MPEP 2173.02. Similarly, "a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible". *See* MPEP 2173.02. (citing *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004).

Applicants respectfully believe that "low" water content is readily discernable to those of ordinary skill in the excipient industry. For example, United States Patent No. 6,710,050 (cited by the Office) and United States Patent No. 7,090,870 (obtained by brief search of patents in the relevant art) show that *low water content* is understood to be below about 1% water (see col. 3, lines 23-28 and col. 4, line 9 of the referenced patents respectively).

In an effort to expedite prosecution, however, Applicants have amended Claim 6 to clarify that low water content is below about 1% water, and cancelled Claims 11 and 12 without disclaimer. Applicants respectfully believe the Office's concerns have been addressed and request favorable reconsideration.

35 U.S.C. §103(a) rejections

Claims 6, 7, 9, 11-13, 16, and 28 were rejected under 35 U.S.C. §103 as obvious over WO 9741097 ("Lohray") in view of U.S. Patent No. 6,886,867 ("Staniforth") in further view of U.S. Patent No. 4,280,997 ("Van Leverink").

The Office acknowledges that Lohray does not teach "**low water** content comprising **anhydrous lactose** and **microcrystalline cellulose** and proportions of excipients set forth in claim 9 and formulating tablet by direct compression set forth in Claim 28" (emphasis provided by the Office). The Office contends that Van Leverink can be used to supplement Lohray's *anhydrous lactose* deficiency and that Staniforth can be used to supplement Lohray's *microcrystalline cellulose* deficiency. Applicants respectfully disagree and request favorable reconsideration for the reasons below.

"It is improper to combine references where the references teach away from their combination". *See* MPEP 2145 (citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Applicants respectfully submit that Van Leverink and Staniforth teach away from the combination being used by the Office to allege obviousness of the presently claimed invention.

Van Leverink is directed to an extrusion process for the preparation of anhydrous stable lactose. Van Leverink discloses that "[b]ecause in the process of the invention **water is not added**, an anhydrous product can be obtained **without after-drying**..." (col. 2, lines 65-66, emphasis added). After-drying is detrimental, Van Leverink discloses, because "after-dried products often show **unacceptable hygroscopic properties**, possibly as a result of the presence of unstable or amorphous forms of lactose" (col. 2, lines 62-64, emphasis added).

Staniforth is directed to an agglomerated microcrystalline cellulose excipient. Staniforth, in contrast to Van Leverink, discloses that the microcrystalline cellulose is [accomplished] by preparing **an aqueous slurry**...and **drying the mixture** in a manner which [reduces undesirable hydrogen bonding]" (col. 6, lines 36-49, emphasis added). Staniforth does disclose that "further materials...may be included in the aqueous slurry" and that "in addition to one or more active ingredients,...inert pharmaceutical filler (diluent) material can be included in the final product" (col. 15, lines 1-19). Staniforth also lists "lactose" as one of many "inert pharmaceutical fillers" that may be used (col. 15, lines 22-23).

Applicants respectfully submit that, based on Van Leverink's teaching away from adding water and after-drying, one having Staniforth and Van Leverink would, at most, only be motivated to use lactose as disclosed by Staniforth. There would be no motivation to make the currently claimed combination including *anhydrous* lactose. Nor would their be any expectation that stability of the composition would be improved, particularly in light of Van Leverink's disclosure that adding water and after-drying can cause "unacceptable hygroscopic properties" for anhydrous lactose.

For at least these reasons, Applicants respectfully request favorable reconsideration of Claims 6, 7, 9, 11-13, 16 and 28.

Provisional obviousness-type double patenting rejections

Claims 6, 7, 9, 11-13, 16, and 28-31 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-21 of copending Application No. 10/699,043.

Enclosed herewith is properly executed PTO/SB/25 and associated fee to overcome the rejection.

Obviousness-type double patenting rejections

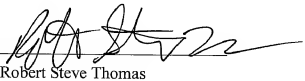
Claims 6, 7, 9, 11-13, 16, and 28-31 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of United States Patent No. 6,710,050.

Enclosed herewith is properly executed PTO/SB/26 and associated fee to overcome the rejection.

Conclusion

Applicants believe that all remaining claims are in condition for allowance, and such action is respectfully requested. Should the Office determine there are outstanding issues, Applicants' representative welcomes a telephone call to facilitate timely and efficient prosecution.

Respectfully submitted,

By 

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